APR 16 2012

510(k) Summary
Codman® Quad-Lock™ Sterilization Container Systems

Date Prepared: January 13, 2011

Company Name: Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person Megan Herman
Regulatory Affairs Specialist
Telephone Number: (508) 828-3571
Fax Number: (508) 977-6428

Device Proprietary Name: Codman® Quad-Lock™ Sterilization Container Systems
Device Common Name: Container Sterilization System

Classification Name: Container Sterilization System

Device Classification: Class II (21 CFR 880.6850) (KCT)

Type of 510(k) Submission: Traditional 510(k)

Basis for Submission: Expand Indications for Use

Predicate Device(s): K092437 Codman® Sterilization Container

Device Description

The CODMAN QUAD-LOCK Sterilization Container System provides a means to organize and protect stainless steel, aluminum, titanium, plastic and silicone surgical instruments during sterilization and storage. The container lids, safety covers, and container bottoms are made from aluminum. The safety covers help ensure sterility during storage and protect the container lid when the containers are stacked. The Container System includes the container base, lid, safety cover, filters and other accessories.

Indications for Use

The CODMAN QUAD-LOCK Sterilization Container System is indicated for use by hospitals and by health care facilities to:

- organize and protect stainless steel, aluminum, titanium, plastic and silicone surgical instruments that will be sterilized
- allow sterilization of the contained instruments by prevacuum steam sterilization (validated parameters shown in Table 1)

• maintain the sterility of the contents for up to 180 days during storage and transport within the health care facility, as long as the integrity of the container has not been compromised

The system has not been tested for maintenance of sterility after transportation outside the health care facility.

The system is intended for use with stainless steel, aluminum, titanium, plastic and silicone surgical instruments.

Lumen inner diameter	3mm or larger
Lumen length	400mm or less (medium and large size containers) 250mm or less (small size containers)
Quantity	Up to 4 lumen instruments per container

The system is not intended for the sterilization of endoscopes.

For effective sterilization and drying of any size CODMAN QUAD-LOCK Sterilization Container, the recommended maximum combined weight of the single container, lid, basket/tray and basket/tray contents is 25 lb. (11.3 kg).

Table 1
Sterilization Parameters

Cycle Type	Temperature	Exposure Time	Dry Time
Prevacuum	132°C	4 minutes	30 minutes

The Codman® Quad-Lock™ Sterilization Container Systems can be stacked during sterilization with up to three containers.

Technological Characteristics

The technological characteristics of this device, including design and materials, are identical to the predicate device, Codman® Sterilization Container (K092437).

Non-Clinical Performance Testing

Testing has been completed and supports the safety and effectiveness of the proposed device for its proposed intended uses.

Clinical Performance Testing

The intention of this Traditional 510(k) is to expand the cleared Indications for Use for the Codman® Quad-Lock™ Sterilization Container Systems. The Codman Quad-Lock Sterilization Container Systems were originally cleared by the FDA on March 25, 2010 under 510(k) K092437. There were no Clinical Tests performed.

Statement of Substantial Equivalence

The Codman® Quad-Lock™ Sterilization Container Systems are substantially equivalent to the Codman® Sterilization Container (K092437) based on similarities in intended use, design, principles of operation, and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Megan Herman
Regulatory Affairs Specialist
Codman & Shurtleff, Incorporated
325 Paramount Drive
Raynham, Massachusetts 02767-0350

APR 16 2012

Re: K120117
Trade/Device Name: Codman® Quad-Lock™ Sterilization Container Systems
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap.
Regulatory Class: II
Product Code: KCT
Dated: March 21, 2012
Received: March 22, 2012

Dear Ms. Herman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120117

Device Name: Codman® Quad-Lock™ Sterilization Container Systems

Indications For Use:

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Lumen inner diameter	3mm or larger
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Quantity	Up to 4 lumen instruments per container

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For effective sterilization and drying of any size CODMAN QUAD-LOCK Sterilization Container, the recommended maximum combined weight of the single container, lid, basket/tray and basket/tray contents is 25 lb. (11.3 kg).

Table 1 Sterilization Parameters			
Cycle Type	**Temperature**	**Exposure Time**	**Dry Time**
Prevacuum	132°C	4 minutes	30 minutes

The Codman® Quad-Lock™ Sterilization Container Systems can be stacked during sterilization with up to three containers.

Codman® Quad-Lock™ Sterilization Container Systems consists of a basket, container base, wire base, protective mats, filter lids, security lids, filters, security seals, labels, ergonomic hand grips and accessories. The following tables give a complete list of available products:

FILTER BOTTOM Container Base

Product Code	Height
Full Length	
508726	100mm (4 inch)
508727	135mm (5 inch)
508728	150mm (6 inch)
508729	200mm (8 inch)
508730	260mm (10 inch)
Product Code	Height
Three-Quarter Length	
508736	100mm (4 inch)
508737	135mm (5 inch)
508738	150mm (6 inch)
Product Code	Height
Half Length	
508731	100mm (4 inch)
508732	135mm (5 inch)
508733	150mm (6 inch)
508734	200mm (8 inch)
508735	260mm (10 inch)

SOLID BOTTOM Container Base

Product Code	Height
Full Length	
508739	100mm (4 inch)
508740	135mm (5 inch)
508741	150mm (6 inch)
508742	200mm (8 inch)
508743	260mm (10 inch)
Product Code	Height
Three-Quarter Length	
508749	100mm (4 inch)
508750	135mm (5 inch)
508751	150mm (6 inch)
Product Code	Height
Half Length	
508744	100mm (4 inch)
508745	135mm (5 inch)
508746	150mm (6 inch)
508747	200 (8 inch)
508748	260 (10 inch)

Filter Lids

Product Code	Color
Full Length	
508944	Grey
508945	Yellow
508946	Green
508947	Blue
508948	Red
508949	Black
Product Code	Color
Three-Quarter Length	
508956	Grey
508957	Yellow
508958	Green
508959	Blue
508960	Red
508961	Black
Product Code	Color
Half Length	
508950	Grey
508951	Yellow
508952	Green
508953	Blue
508954	Red
508955	Black

Security Lids

Product Code	Color
Full Length	
508869	Grey
508870	Yellow
508871	Green
508872	Blue
508873	Red
508874	Black
Product Code	Color
Three-Quarter Length	
508881	Grey
508882	Yellow
508883	Green
508884	Blue
508885	Red
508886	Black
Product Code	Color
Half Length	
508875	Grey
508876	Yellow
508877	Green
508878	Blue
508879	Red
50880	Black

Basket Configurations

Product Code	Height
Full Length	
508500	30mm (1 inch)
508501	50mm (2 inch)
508502	70mm (3 inch)
508503	100mm (4 inch)
Product Code	Height
Three-Quarter Length	
508508	30mm (1 inch)
508509	50mm (2 inch)
508510	70mm (3 inch)
508511	100mm (4 inch)
Product Code	Height
Half Length	
508504	30mm (1 inch)
508505	50mm (2 inch)
508506	70mm (3 inch)
508507	100mm (4 inch)

Wire Base Configurations

Product Code	Length	Height
508512	Half	26mm (1 inch)
508513	Three-Quarter	26mm (1 inch)
508514	Full	26mm (1 inch)

Protective Mat Configurations

Product Code	Length
508550	Half
508551	Three-Quarter
508552	Full

Accessories

Product Code	Description
509018	Holding Pin for Divider – 1 Each (Use with 509026 to 509029)
509019	Holding Pin for Instruments 26mm (1 inch) (1 Each)
509020	Basket Handle Tag (1 Each)
509021	Spring Clip 7mm - 12mm (¼ inch - ½ inch)
509022	Spring Clip 12mm - 16mm (½ inch - ¾ inch)
509023	Spring Clip 16mm - 26mm (¾ inch - 1 inch)
509024	Spring Clip 26mm - 36mm (1 inch - 1½ inch)
509025	Spring Clip 36mm - 45mm (1½ inch - 1¾ inch)
509026	Divider 50mm x 20mm (2 inch x ¾ inch) (Use with two 509018)
509027	Divider 130mm x 20mm (5 inch x ¾ inch) (Use with two 509018)
509028	Divider 225mm x 20mm (9 inch x ¾ inch) (Use with two 509018)
509029	Divider 460mm x 20mm (18 inch x ¾ inch) (Use with two 509018)
509030	Polymer Spacer – 1 Each (Use with 509031 and 509032)
509031	Sliding Rail for Polymer Spacer 230mm (9 inch) (Use with 509030)
509032	Sliding Rail for Polymer Spacer 470mm (18 ½ inch) (Use with 509030)
509033	Limiting Bar 230mm (9 inch) (Screws to Basket)
509034	Limiting Bar 470mm (18 ½ inch) (Screws to Basket)
509035	Spiral Holding Device - Double 230mm (9 inch) (Screws to Basket)
509036	Spiral Holding Device - Single 130mm (5 inch) (Screws to Basket)
509037	Limiting Bar Right Angle 110mm (4 ½ inch) (Screws to Basket)
509038	Limiting Bar Right Angle 170mm (6 ½ inch) (Screws to Basket)
509039	Limiting Bar Right Angle 230mm (9 inch) (Screws to Basket)
509040	Limiting Bar Right Angle 470mm (18 ½ inch) (Screws to Basket)
509041	Spiral Divider with Limiting Bar 130mm x 230mm (5 inch x 9 inch)
509042	Spiral Divider - Double 230mm (9 inch) (Use with 509018)
509043	Spiral Divider - Single 130mm (5 inch) (Use with 509018)
509100	Universal Rongeur Instrument Holder

Ergonomic Silicone Hand Grips (Pair)

Product Code	Length
509012	Red
509013	Blue
509014	Green
509015	Yellow
509016	Grey
509017	Black

Aluminum Name Plates (1 Each)

Product Code	Length
509000	Red
509001	Blue
509002	Green
509003	Yellow
509004	Grey
509005	Black

Single Use Products

Product Code	Description	Quantity
509006	Paper Label with Indicator (small)	250
509007	Paper Label with Indicator (large)	250
509008	Security Seal Single-Use Only - Blue	100
509010	Filter – Single-Use Only	1000
509044	Filter Retention Disc	1

Mahip Sanguduri 4/13/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120117

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)